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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|----------------|----------------------|---------------------|------------------|
| 10/661,989 | 09/11/2003 | Judith Franks-Farah | 0110430-031 | 9330 |
| 7 | 590 04/14/2004 | | EXAM | INER |
| Bell, Boyd & Lloyd LLC | | | BUI, LUAN KIM | |
| P.O. Box 1135 Chicago, IL 60690-1135 | | | ART UNIT | PAPER NUMBER |
| | | | 3728 | |

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) |
|--|---|--|
| • . | 10/661,989 | FRANKS-FARAH ET AL. |
| Office Action Summary | Examiner | Art Unit |
| | Luan K Bui | 3728 |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with | n the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a rep within the statutory minimum of thirty will apply and will expire SIX (6) MONTI cause the application to become ABA | oly be timely filed (30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on | | |
| 2a) This action is FINAL . 2b) ⊠ This | action is non-final. | |
| 3) Since this application is in condition for allowar | • | • • |
| closed in accordance with the practice under E | x parte Quayle, 1935 C.D. | 11, 453 O.G. 213. |
| Disposition of Claims | | |
| 4)⊠ Claim(s) <u>1-8</u> is/are pending in the application. | 4 | |
| 4a) Of the above claim(s) is/are withdraw | vn from consideration. | |
| 5) Claim(s) is/are allowed. | | |
| 6)⊠ Claim(s) <u>1-8</u> is/are rejected. | | |
| 7) Claim(s) is/are objected to. | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | |
| Application Papers | | : |
| 9) The specification is objected to by the Examine | r. | |
| 10) The drawing(s) filed on is/are: a) acce | | y the Examiner. |
| Applicant may not request that any objection to the | | |
| Replacement drawing sheet(s) including the correcti | ion is required if the drawing(s |) is objected to. See 37 CFR 1.121(d). |
| 11)☐ The oath or declaration is objected to by the Ex | aminer. Note the attached | Office Action or form PTO-152. |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: | priority under 35 U.S.C. § 1 | 119(a)-(d) or (f). |
| 1. Certified copies of the priority documents | | |
| 2. Certified copies of the priority documents | | |
| 3. Copies of the certified copies of the prior | • | eceived in this National Stage |
| application from the International Bureau | | oppised. |
| * See the attached detailed Office action for a list of | or the certified copies hot re | cceiveu. |
| Attachment(s) | | |
| 1) Notice of References Cited (PTO-892) | | mmary (PTO-413) |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | | Mail Date ormal Patent Application (PTO-152) |
| Paper No(s)/Mail Date | 6) Other: | • |
| | | |

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A telephone interview between the Applicant's representative (Mr. Adam Masia) and Examiner (Luan Bui) on 4/9/2004 that the Mr. Masia is agreed to amend claim 3 to include --at least one container for holding the system-- Applicant is required to amend claim 3 to include the above phrase in response to this office action.

Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daneshvar (5,582,599) in view of Official Notice. Daneshvar discloses a system comprising a cover (18), at least one male cathether (44), a lubricant gel (29, 30) and a series of lines, markings and figures that will allow special directions or instructions to be communicated to the users (Figure 6 and column 4, lines 11 to column 5 lines 25). To the extent that Daneshvar fails to show at least one container for holding the system, Official Notice is taken of the old and conventional practice of providing at least one container for holding at least one item and at least one set of instructions for using the items to providing more convenience for the users. It would have been obvious to one having ordinary skill in the art in view of Official Notice to modify the system of Daneshvar so it includes at least one container for holding the system for better protecting the system during shipping and handling.

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Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 4. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,640,976. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations in the claims of the instant patent application are fully disclosed by the patents.
- 5. Claims 1-8 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 09/879,230. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one having ordinary skill in the art at the time the invention was made to replace a female catheter to a male catheter to allow the system for holding a different type of catheter.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is (703) 305-5861. If in receiving this Office Action, it is apparent to Applicant that certain documents are missing from the record for example copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to TC 3700 Customer Service at (703) 306-5648.

Any inquiry of a general nature or relating to the status of this application should be directed to the Customer Service whose telephone number is (703) 872-9301. Facsimile correspondence for this application should be sent to (703) 872-9306 for Formal papers and After Final communications.

lkb April 13, 2004

Luan K. Bui Primary Examiner